

# **Exhibit 2**

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Page 329

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC. : MDL NO. 2327  
PELVIC REPAIR SYSTEM :  
PRODUCTS LIABILITY :  
LITIGATION :

- - -

THIS DOCUMENT RELATES TO ALL CASES  
AND VARIOUS OTHER CROSS-NOTICED ACTIONS

- - -

Wednesday, August 15, 2013

VOLUME II

- - -

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Videotaped Deposition of THOMAS A.  
BARBOLT, Ph.D., held at Riker Danzig Scherer Hyland  
Perretti LLP, Headquarters Plaza, One Speedwell Avenue,  
Morristown, New Jersey, on the above date, beginning at  
9:03 a.m., before Margaret M. Reihl, a Certified  
Realtime Reporter, Certified Court Reporter, and Notary  
Public.

- - -

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Page 367

1 appropriate animal model, right?

2 MR. THOMAS: Object to the form of the  
3 question.

4 THE WITNESS: The information gained  
5 from the suture strand in the back of a rat gives a lot  
6 of information about the potential for carcinogenicity  
7 of any device.

8 BY MR. THORNBURGH:

9 Q. Doesn't give you the same information?

10 A. That's correct.

11 MR. THORNBURGH: Mary Ellen, were you  
12 able to identify what document this came from?

13 MS. SCALERA: Ms. Stigman is trying to  
14 look it up on the system. I'll let you know as soon as  
15 possible.

16 BY MR. THORNBURGH:

17 Q. We talked yesterday somewhat about your  
18 involvement with or your involvement with a discussion  
19 at least that you had with David Robinson and the risk  
20 of -- the risk in humans of particle loss or fraying.

21 Do you recall that discussion?

22 A. I recall some e-mails. I don't know that I  
23 responded in that e-mail string. I don't recall, but I  
24 do recall generally what you're talking about.

25 (Document marked for identification as

Confidential - Subject to Protective Order

Page 368

1                   Deposition Exhibit No. T-2115.)

2                   MR. THOMAS: Just for the record, you've  
3                   marked this as 2115?

4                   BY MR. THORNBURGH:

5                   Q.           Yeah, I'm sorry. It's been marked -- the  
6                   exhibit has been marked 2115 ETH.MESH.00863391.

7                   And you see this is an e-mail from Dan Smith on  
8                   February 27th, 2004, right?

9                   A.           Yes.

10                  Q.           And the subject line is "2 TVT complaints  
11                  concerning allegedly brittle mesh."

12                  You see that?

13                  A.           Yes.

14                  Q.           And as we did yesterday, I'd would like to turn  
15                  to -- turn to the second page and we'll work backwards.

16                  And the original e-mail is from Bernhard  
17                  Fischer to Janice Burns with that same subject line,  
18                  the importance is high, and Bernhard says or  
19                  Mr. Fischer says to Janice Burns or discusses with  
20                  Janice Burns two TVT complaints regarding mesh TVT Blue  
21                  and the TVT obturator system.

22                  And if you look down at the paragraph after  
23                  that it says, "Dr. Mirna noticed that small blue  
24                  particles kept falling off the mesh, as if the mesh was  
25                  as he put it 'brittle'."

Confidential - Subject to Protective Order

Page 369

1 Do you see that?

2 A. Yes.

3 Q. And then below that it says, "since our mesh is  
4 now blue, would it be possible that this was always the  
5 case but now it is simply visible as opposed to before  
6 the introduction of TVT Blue?"

7 Do you see that?

8 A. Yes.

9 Q. Okay. So there's a discussion about complaints  
10 that are coming in about the TVT losing particles,  
11 right?

12 A. Yes.

13 Q. And you recall that being an issue when you  
14 worked for Ethicon, don't you?

15 A. Yeah, I recall some discussion of that.

16 Q. Well, if you turn to the front page, Dan  
17 Smith's response, he says, "this is not new, and was  
18 exactly the original issue that stopped TVT Blue for  
19 months. The fix (I'm not sure how complete) is to cut  
20 the mesh using ultrasonics, but it has not been  
21 validated and I'm not sure where it sits on the  
22 Operations priority list. I recall it was scheduled  
23 for mid to end of 2004."

24 He goes on to say, I believe that the board has  
25 to set a directive that can be filtered down to the

Confidential - Subject to Protective Order

Page 370

1    reps, saying it's OK and it's not an issue, same as TVT  
2    clear except you can see it. By the way, you can also  
3    see it in the packages of the pieces as the pieces fall  
4    out of the sheath splits.

5            This is not going away any time soon and  
6    competition will have a field day, major damage control  
7    offensive needs to start to educate the reps and  
8    surgeons up front that they will see blue shit and it  
9    is okay. This is why I wanted to launch TVTO in clear.

10           You see that?

11    A.        Yes, I see that.

12    Q.        Did you ever do any preclinical -- or did Dan  
13    Smith or anybody ever ask you to do a preclinical study  
14    of the blue shit that's falling off the mesh?

15    A.        No, I don't think so.

16    Q.        Instead Dan Smith -- you know Dan Smith, right?

17    A.        Yeah, I know Dan.

18    Q.        He's not a doctor, right?

19    A.        He's a project leader type.

20    Q.        Not a doctor, right?

21    A.        Not an MD.

22    Q.        He's in the research and development  
23    department?

24    A.        Yes, I guess in the project management side of  
25    things.

Confidential - Subject to Protective Order

Page 371

1 Q. And Dan Smith rather than -- Dan Smith never  
2 came to you and said, hey, Dr. Barbolt, why don't we  
3 test these blue particles that are falling off of our  
4 meshes to make sure that there's not an increased risk  
5 to patients, right?

6 A. I don't recall whether or not he did.

7 Q. Well, you didn't do a test, right?

8 MR. THOMAS: Object to the form of the  
9 question.

10 THE WITNESS: I did not.

11 BY MR. THORNBURGH:

12 Q. That would have been something you could have  
13 done?

14 MR. THOMAS: Object to the form of the  
15 question.

16 THE WITNESS: As I read this memo,  
17 frankly, I tend to agree that the small particles of  
18 polypropylene may have always been there but were clear  
19 and gone unnoticed.

20 BY MR. THORNBURGH:

21 Q. That wasn't my question, Doctor.

22 My question to you was you could have tested it  
23 preclinically in animals to see what the additional  
24 risk of this -- these particles falling off of the  
25 product is, right?

Confidential - Subject to Protective Order

Page 372

1 A. TVT tape was tested in a one-month study.

2 Q. My question was specifically looking at the  
3 particles, you could have done that?

4 A. Although it wasn't blue at that time, there  
5 were no particles of clear observed in the tissue  
6 sections either.

7 Q. Because you couldn't see it. Once they dyed it  
8 blue, then all of a sudden, you can see it. It becomes  
9 obvious. Dan Smith says it's been there all along, but  
10 now you can see it because we dyed it blue.

11 A. Well, you would see the clear in a tissue  
12 section.

13 Q. Dan Smith is saying this has been -- this is  
14 not new and was exactly the original issue that stopped  
15 TVT blue for months.

16 Do you think the blue pigmented dying of the  
17 filaments somehow caused the mesh to start to lose  
18 particles?

19 A. No.

20 Q. It's because now you could see it, right?

21 A. I think so.

22 Q. And so my question to you still remains, you  
23 could have done a study preclinically to review what  
24 the additional risk was associated with these particles  
25 that are falling off, right?



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Page 373

1 MR. THOMAS: Object to the form of the  
2 question.

3 THE WITNESS: Well, we did a one-month  
4 intramuscular implantation study, and particles of  
5 clear were not observed.

6 BY MR. THORNBURGH

7 Q. Did you --

8 A. That tells me that the risk would be very small  
9 or nonexistent.

10 Q. Did you ever take the particles, the blue shit  
11 that Dan Smith is talking about, and cut open the back  
12 end of a rat, put those particles inside the rat to see  
13 what the inflammatory response would be?

14 A. Such a study was done in the one-month  
15 intramuscular study. If there were particles present,  
16 they would have been observed in the tissue section,  
17 and we would have seen a very similar tissue reaction  
18 to the particles as what we see to the filaments of the  
19 mesh.

20 Q. That wasn't my question.

21 My question was did you ever just take the  
22 particles, cut open the back end I think you called it  
23 the ass end of a rat, take that -- as Dan Smith calls  
24 it the blue shit, put it in the rat and see if there is  
25 an inflammatory response to the particles?

Confidential - Subject to Protective Order

Page 374

1 A. No.

2 MR. THORNBURGH: I'm going to go ahead  
3 and mark a document internal Ethicon document as  
4 Exhibit Number 2116, ETH.MESH.02180828.

5 (Document marked for identification as  
6 Deposition Exhibit No. T-2116.)

7 MR. THORNBURGH: And I'll go ahead and  
8 also mark a document that goes with it, the ETH.MESH  
9 number 02180828, and it's been marked as Exhibit Number  
10 2117 -- sorry, that's not right.

11 I've marked the document with  
12 ETH.MESH.02180833 as Exhibit 2117.

13 MR. THOMAS: I need one more page,  
14 please.

15 (Document marked for identification as  
16 Deposition Exhibit No. T-2117.)

17 BY MR. THORNBURGH:

18 Q. So if you turn to Exhibit 2116, it's a -- first  
19 off, at the top of it is a letterhead -- it's a  
20 letterhead telefax and it says "Johnson & Johnson  
21 Medical Switzerland."

22 You see that?

23 A. Yes.

24 Q. And then the date is November 10th, 2004, and  
25 it's to a David Menneret from a person named Sibylle

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Page 375

1 Basso or Basso, and subject is TVT Blue.

2 You see that?

3 A. Yes.

4 Q. It says, please see the attached letter of  
5 Mister PD Dr. Eberhard. (He is one of our most urgent  
6 customers). Hope you understand a little German.

7 You see that?

8 A. Yes.

9 Q. "Is there a process ongoing concerning the  
10 production of TVT Blue tape? Do you have received any  
11 other comments like that one? Is the problem  
12 communicated to the organization (Steve Belle)? If  
13 not, what could we do?"

14 So if we turn now to the translated letter from  
15 Dr. Eberhard, this says, Dear Emilie, please find  
16 attached a TVT tape --

17 A. Hang on.

18 Q. Sorry. It's on Exhibit 2117.

19 A. Okay.

20 Q. "Please find attached a TVT tape, which was  
21 used as a demo unit for patients before they have their  
22 operation. Already at the operation it is embarrassing  
23 to see how the tape is crumbling. But it gets worse if  
24 there is a stretch on the tape. It is urgent that  
25 Johnson & Johnson quickly produce a tape that is solid

Confidential - Subject to Protective Order

Page 376

1 and weaved."

2 You see that?

3 A. Yes.

4 Q. Okay. And this is one of the problems that  
5 we've just discussed, and there's other complaints with  
6 the tape appearing as it's crumbling or appearing as  
7 it's brittle or the particles falling off of the  
8 product, right?

9 MR. THOMAS: Object to form of the  
10 question.

11 BY MR. THORNBURGH:

12 Q. Exhibit 2115?

13 A. I was looking at Exhibit 2116, and I see a  
14 picture of the tape at the bottom, and it looks more  
15 than just some particles falling off. It looks  
16 different than I would have expected.

17 Q. Why don't we go ahead and pull up the tape that  
18 you're referring to. Now, if you go to Exhibit 2116,  
19 that's the picture that you're referring to, right?

20 A. No, the one on the previous page.

21 Q. Okay. So if you go to the previous page --

22 A. Yes.

23 Q. -- you blow up that picture at the bottom.

24 So a picture was provided in the original  
25 letter from Dr. Eberhard, correct?

Confidential - Subject to Protective Order

Page 377

1 MR. THOMAS: Object to form of the  
2 question.

3 BY MR. THORNBURGH:

4 Q. According to this exhibit, right?

5 A. As indicated in these documents.

6 Q. And look at that picture. Did you ever test  
7 what that type of mesh with all the frayed edges -- I  
8 mean, it looks like a saw, right?

9 MR. THOMAS: Object to the form of the  
10 question.

11 THE WITNESS: As indicated in the German  
12 -- I'm just reading these documents, I've never seen  
13 these before.

14 BY MR. THORNBURGH:

15 Q. Right, but --

16 MR. THOMAS: Let him finish.

17 THE WITNESS: I've never seen them  
18 before. I'm reading them, and as an scientist, I'm  
19 offering up an interpretation, and I also note in the  
20 German response that the TVT tape was used as a demo  
21 unit. So I'm not sure how much handling that tape has  
22 had, to have that sort of appearance.

23 Q. Did Dr. Eberhard's letter says -- let's keep  
24 that picture up there, first off. Let's talk about the  
25 picture.

Confidential - Subject to Protective Order

Page 378

1           You see that tape? You can look at the screen,  
2 if you want, Doctor?

3     A.       Yes, I see it.

4     Q.       That's embarrassing, isn't it?

5                     MR. THOMAS: Object to the form of the  
6 question.

7                     THE WITNESS: I'm not sure what was done  
8 to this tape to make it look this way.

9     BY MR. THORNBURGH:

10    Q.       Dr. Eberhard says, already at the operation, it  
11 is embarrassing to see how the tape is crumbling,  
12 right?

13                    MR. THOMAS: Object to the form of the  
14 question.

15                    THE WITNESS: I see the words.

16    BY MR. THORNBURGH:

17    Q.       And then he sends this picture of the tape that  
18 he was referencing in his letter, which is all torn up  
19 with all these frayed edges, and it looks like a saw at  
20 the edges of that tape, doesn't it?

21                    MR. THOMAS: Object to the form of the  
22 question.

23                    THE WITNESS: It looks broken down.

24    BY MR. THORNBURGH:

25    Q.       Is that the type of product Ethicon was

Confidential - Subject to Protective Order

Page 379

1     implanting permanently in the vaginas of women all  
2     across the world?

3                     MR. THOMAS: Object to the form of the  
4     question.

5                     THE WITNESS: It says that it's used as  
6     a demo unit. I'm not sure how much stretching and  
7     handling it's had.

8     BY MR. THORNBURGH:

9     Q.             That's the tape -- according to Dr. Eberhard,  
10    that's the TVT tape that he got from Ethicon and was  
11    preparing for an operation, and it was all torn up,  
12    broken down with all these frayed edges, frayed in such  
13    a way that it looks like a saw, right?

14                    MR. THOMAS: Object to the form of the  
15    question.

16                    THE WITNESS: I hear your description of  
17    it. I'm not sure how it was handled to make it look  
18    that way.

19    BY MR. THORNBURGH:

20    Q.             Well, you can look at it, it's on the screen.

21    A.             I can see it in the documents.

22    Q.             Well, I got it blown up for you, Doctor, on the  
23    screen, if you want to take a look at it?

24    A.             My eyes are pretty good for that size of  
25    object.

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Page 380

1 Q. That's pretty nasty looking mesh, isn't it?

2 MR. THOMAS: Object to form of the  
3 question.

4 THE WITNESS: It is what it is.

5 BY MR. THORNBURGH:

6 Q. And women are being implanted with Ethicon's  
7 TVT tape all across the world, aren't they?

8 MR. THOMAS: Object to the form of the  
9 question.

10 THE WITNESS: I don't think the tape  
11 looks like that when it comes out of the package.

12 BY MR. THORNBURGH:

13 Q. Women in New Jersey, women in Florida, women in  
14 California, women in West Virginia are being implanted  
15 with this stuff, this TVT mesh, right?

16 MR. THOMAS: Object to the form of the  
17 question.

18 THE WITNESS: I don't think it looks  
19 like that when it comes out of the package for  
20 implantation.

21 BY MR. THORNBURGH:

22 Q. Dr. Eberhard says it's embarrassing, the tape  
23 is crumbling. That's what Dr. Eberhard said. He's a  
24 doctor that's actually treating women, right?

25 MR. THOMAS: Object to form of the



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Page 381

1 question.

2 THE WITNESS: He also says it's used as  
3 a demo unit.

4 BY MR. THORNBURGH:

5 Q. He also says it's embarrassing, doesn't he?

6 A. I see those words.

7 Q. And you never tested in women what the risk of  
8 particle loss or fraying was, you never tested --  
9 strike that. Let me ask a better question, because I  
10 know it was poorly started.

11 You never tested in animals what the additional  
12 risk of the particle loss was, right?

13 MR. THOMAS: Object to form of the  
14 question.

15 THE WITNESS: Other than the 28-day  
16 study.

17 BY MR. THORNBURGH:

18 Q. Right, but you didn't take the particles and  
19 dump it into the back end of a rat and see what that  
20 risk would be, correct?

21 A. No, we did not.

22 Q. You didn't look at what the risk of --  
23 specifically what the risk of this nasty crumbling tape  
24 is even in rats or guinea pigs or shoot(sic), did you?

25 MR. THOMAS: Object to the form of the

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Page 382

1 question.

2 THE WITNESS: I would say that a bunch  
3 of particles are not implanted in patients. The tape  
4 is implanted in patients and any associated particles.  
5 Those particles, although clear, would have been  
6 observed in the tissue sections in the 28-day study.

7 BY MR. THORNBURGH:

8 Q. 8.5% particle loss, almost 10% of y'all's  
9 meshes was falling apart into these little particles  
10 and crumbling, as Dr. Eberhard says, right?

11 MR. THOMAS: Object to the form of the  
12 question.

13 THE WITNESS: I see his words in this  
14 memo.

15 BY MR. THORNBURGH:

16 Q. Did you know that 8.5%, almost 10% of the mesh  
17 was lost to particles?

18 MR. THOMAS: Object to form of the  
19 question.

20 THE WITNESS: I didn't know that number.

21 BY MR. THORNBURGH:

22 Q. Did you take 8.5% of the mesh, the blue shit  
23 that Dan Smith was talking about, throw it in the back  
24 end of a rat to see what the additional inflammatory  
25 response would be to those particles?

Confidential - Subject to Protective Order

Page 383

1 MR. THOMAS: Object to form of the  
2 question.

3 THE WITNESS: No, other than testing the  
4 tape and any associated particles.

5 BY MR. THORNBURGH:

6 Q. Exhibit 2117, Dr. Eberhard says, I can't  
7 understand that no one will solve that problem for such  
8 a long time. At the latest, as the tape has becoming  
9 blue, everyone has realized that the quality of tape  
10 is, in Dr. Eberhard's words, terrible, right?

11 MR. THOMAS: Object to form of the  
12 question.

13 BY MR. THORNBURGH:

14 Q. That's what he writes?

15 A. That's what he writes.

16 Q. To Johnson & Johnson?

17 MR. THOMAS: Object to form of the  
18 question.

19 THE WITNESS: That's what it looks like.

20 BY MR. THORNBURGH:

21 Q. And it says, please see the picture of the  
22 I-STOP tape of Hausmann. A tape has to be weaved and  
23 should not crumble. Please try one and you will see  
24 that the tape is crumbling.

25 That's what Eberhard says, right?

Confidential - Subject to Protective Order

Page 384

1 MR. THOMAS: Object to form of the  
2 question.

3 THE WITNESS: Yes.

4 BY MR. THORNBURGH:

5 Q. He's an important doctor in Germany, right?

6 MR. THOMAS: Object.

7 THE WITNESS: I don't know him.

8 MR. THOMAS: Object to the form of the  
9 question.

10 Are you finished with that exhibit?

11 MR. THORNBURGH: Yes.

12 MR. THOMAS: We went seven hours  
13 yesterday. We've gone another hour today, which is  
14 more than the seven hours the MDL allows.

15 MR. THORNBURGH: I've got some more  
16 questioning.

17 MR. THOMAS: Well, I understand that.  
18 How much do you have?

19 MR. THORNBURGH: This is -- I'm going  
20 through these exhibits pretty fast.

21 MR. THOMAS: I just ask you how much you  
22 have?

23 MR. THORNBURGH: I don't know. I can't  
24 tell you. Probably at least till noon.

25 MR. THOMAS: Is New Jersey counsel going

Confidential - Subject to Protective Order

Page 385

1 to ask questions today?

2 MR. MUHLSTOCK: I don't expect to. This  
3 is Todd Muhlstock of Sanders Viener Grossman for New  
4 Jersey plaintiffs.

5 MR. THORNBURGH: It may take me all day.  
6 It may take me all day to get through these documents.  
7 I don't know.

8 MS. SCALERA: Can we hear what New  
9 Jersey counsel has to say, please.

10 MR. MUHLSTOCK: The New Jersey  
11 plaintiffs are not prepared to examine the witness  
12 today. It wasn't expected that there would be any time  
13 available and until late yesterday did not know that  
14 there would be time, and, apparently, there may or may  
15 not be. So at this point, we maintain our position  
16 that we will review the transcript and determine  
17 whether we need to continue the deposition at a later  
18 date for the New Jersey plaintiffs.

19 MR. THOMAS: Let's take a break, please.

20 THE VIDEOGRAPHER: Going off the record.  
21 The time is 10:01 a.m.

22 (Brief recess.)

23 (Deposition resumes at 10:15 a.m.)

24 MR. THOMAS: I'm sorry, I didn't catch  
25 counsel for New Jersey's name.

Confidential - Subject to Protective Order

Page 386

1 MR. MUHLSTOCK: Todd Muhlstock,  
2 M-u-h-l-s-t-o-c-k.

3 MR. THOMAS: Thank you.

4 As the parties know, the MDL has been  
5 trying to coordinate depositions of witnesses with New  
6 Jersey. Ethicon has been trying to cooperate with  
7 counsel to provide adequate time for the depositions of  
8 these witnesses. I advised counsel in the MDL,  
9 Mr. Anderson, earlier in the week that unless counsel  
10 for New Jersey was going to participate in the  
11 deposition so we could complete it in the time that was  
12 provided, that we would hold the deposition time to the  
13 seven hours that the federal rules permit and which has  
14 been discussed with the magistrate now on a couple of  
15 occasions.

16 I asked Mr. Thornburgh last night at the  
17 close of the first day when we did six hours 59 minutes  
18 how much time he expected today and I was told about an  
19 hour. I was also told that somebody from New Jersey  
20 would be here today, and I appreciate the fact that,  
21 Mr. Muhlstock, you weren't part of that conversation,  
22 and I appreciate your comments this morning that you  
23 just learned about this and New Jersey is not prepared  
24 to go forward today. But I am concerned about  
25 continuing the MDL deposition.

Confidential - Subject to Protective Order

Page 387

1                   From what Mr. Thornburgh tells me, it  
2 may be the rest of the day and then have to return for  
3 a further deposition of Dr. Barbolt for a fact  
4 deposition. He's been deposed for two days already as  
5 a 30(b)(6). It's anticipated he'll be deposed again,  
6 and Mr. Thornburgh tells me before the break that he  
7 may go all day.

8                   The reason why I went an extra hour  
9 today was to try to accommodate you, and I would like  
10 some commitment from you about what you expect for the  
11 rest of the day so I can determine whether I have to  
12 stop the deposition or whether we can reach an  
13 accommodation.

14                  MR. THORNBURGH: Right. Well, what I  
15 told you was I want to get out of here just as much as  
16 everybody else does, and what I told you was -- well,  
17 yesterday I told you I don't know, it could be an hour,  
18 it could be longer. Today I told you hopefully by  
19 noon, but it could be longer.

20                  What I'm telling you is I want to get  
21 out of here, and I'm going to try to get out of here by  
22 noon. What I don't know is how he's going to respond,  
23 but if you want me to commit to noon, I can commit to  
24 noon. I can get done and out of here by noon, if  
25 that's what you're asking for, but I don't know how

Confidential - Subject to Protective Order

Page 388

1 he's going to respond to questions, and that's part of  
2 an issue.

3 I mean, the first part of this whole  
4 morning the responses that I got were nonresponsive to  
5 the questions I asked, and that can sometimes cause,  
6 you know, a little bit of a delay, but I think we'll be  
7 able to move through these documents rather quickly.

8 MR. THOMAS: Okay, we'll go to noon and  
9 we'll stop at noon.

10 MS. SCALERA: I'd like to put something  
11 on the record for New Jersey. Pursuant to our last  
12 telephonic case management conference with Judge  
13 Higbee, the defendants were supposed to be made aware  
14 of what counsel would be taking the deposition on  
15 behalf of New Jersey counsel prior to the deposition  
16 date, and we were never so told, nor were we ever told  
17 that there would be a problem with New Jersey counsel  
18 attending or completing the deposition today, so I just  
19 want to note for the record that Judge Higbee's  
20 instructions were not followed and that we have no  
21 reason to believe that New Jersey counsel would not  
22 finish the deposition also today.

23 MR. MUHLSTOCK: This is Mr. Muhlstock.  
24 I'm responding regarding the comment that it was  
25 unknown whether we would attend or be able to complete



Confidential - Subject to Protective Order

Page 389

1 today. I don't know what discussions were had with  
2 other people directly on firsthand knowledge, but I was  
3 told that everyone was aware of the situation. I know  
4 for sure that Adam Slater has been involved in this and  
5 had this similar conversation regarding other  
6 depositions, wherein the defendants in the MDL  
7 expressed similar concerns, and he pointed out how it's  
8 impossible for New Jersey attorneys to gauge in advance  
9 how long a particular witness' deposition is going to  
10 take and this one is a perfect example. If we were  
11 prepared to be there yesterday, we wouldn't have been  
12 able to start yesterday. Now we're here today, we  
13 don't know if we would be able to even start today. So  
14 it's, you know, the same conversation has been had  
15 before, and I don't know anything about violating a  
16 specific directive of Judge Higbee. I find it hard to  
17 believe that that was done, but, again, I don't have  
18 firsthand knowledge of it, but I'll look into it and  
19 get back to counsel.

20 MS. SCALERA: Okay. But we expect that  
21 New Jersey -- if New Jersey at all expects to question  
22 this witness, that it be done today when the witness is  
23 present, when MDL counsel finishes, which he has  
24 represented will be at noon. Thank you.

25 MR. MUHLSTOCK: I'm sorry. I didn't

Confidential - Subject to Protective Order

Page 390

1 hear that. Can I have it repeated please or read back.

2 MS. SCALERA: It's going to be read

3 back.

4 (The court reporter read back the record  
5 as requested.)

6 MR. MUHLSTOCK: Well, I'll respond  
7 further on the record, please. As has been discussed  
8 on the record between MDL plaintiff's counsel and  
9 defendant's counsel, there's continuing dispute as to  
10 how quickly this can be done, whether it should have  
11 been done yesterday, whether the witness is answering  
12 the questions asked, which I have to agree he has not  
13 thus far, and that's probably one of the reasons this  
14 is extended to a second day. Whatever defense  
15 counsel's expectations are, our position is what I've  
16 stated our position is, so it appears the expectations  
17 are inconsistent with that, and it is what it is, I  
18 guess.

19 MS. SCALERA: We'll let the record stand  
20 as it is.

21 MR. MUHLSTOCK: Thank you.

22 THE VIDEOGRAPHER: We're back on the  
23 record. Here marks the beginning of Volume 2, Tape  
24 Number 2 in the deposition of Dr. Thomas Barbolt. The  
25 time is 10:22 a.m.

Confidential - Subject to Protective Order

Page 391

1 BY MR. THORNBURGH:

2 Q. I have premarked as Exhibit Number 2118 a  
3 letter dated October 12th, 2005 from Carol Holloway.  
4 Bates number is ETH.MESH.03535750.

5 (Document marked for identification as  
6 Deposition Exhibit No. T-2118.)

7 BY MR. THORNBURGH:

8 Q. Okay. You have this document in front of you,  
9 Exhibit 2118?

10 A. Yes.

11 Q. And this -- in this letter Carol Holloway to  
12 Herve Fournier says, thank you for telling us about  
13 your customer's experience with a TVT device. It was  
14 reported that unraveling and tape became particles.  
15 After implantation of the device the staff discovered  
16 that there was remaining particles in the box. Device  
17 implanted without problems. No consequence. Our  
18 physician -- or sorry -- our physical examination of  
19 the product returned did confirm the fraying. Fraying  
20 is inherent in the product based on the mesh  
21 construction.

22 Did I read that accurately?

23 A. Yes.

24 Q. She goes on to say, "when any amount of tension  
25 is applied to the mesh, fraying occurs." So this is

Confidential - Subject to Protective Order

Page 392

1 yet another complaint being reported to Ethicon or  
2 Gynecare or Johnson & Johnson regarding the problem  
3 that physicians were having in the field who were  
4 implanting patients with Ethicon's device regarding  
5 unraveling and particle loss.

6 That's what this letter would be appear to be,  
7 correct?

8 A. Yes.

9 MR. THOMAS: Object to form of the  
10 question.

11 BY MR. THORNBURGH:

12 Q. And, again, you were working with Gynecare  
13 during this time period, right, with Ethicon?

14 A. Yes, I was at Ethicon at this time.

15 Q. And she goes on say, particles are made of  
16 Prolene as the mesh and so are nonreactive.

17 That's not an accurate statement, is it?

18 MR. THOMAS: Object to form of the  
19 question.

20 THE WITNESS: Reactivity is relative.  
21 For clinicians, nonreactive I believe is appropriate.  
22 For implant pathologists looking at particles in the  
23 body, there may be a mild, chronic inflammatory  
24 reaction, as you would see with the mesh itself.

25

Confidential - Subject to Protective Order

Page 393

1 BY MR. THORNBURGH:

2 Q. Right. So there is going to be a reaction.

3 There's going to be a foreign body reaction, as happens  
4 with every foreign body implanted in the human body,  
5 right?

6 A. Yes.

7 Q. So, in this case, with particles being lost  
8 inside the human body during the implantation of the  
9 mesh, you're going to have increased foreign body  
10 reactions?

11 MR. THOMAS: Object to form of the  
12 question.

13 BY MR. THORNBURGH:

14 Q. Each of those particles that are loose inside  
15 the woman's pelvis are going to trigger an inflammatory  
16 response similar to a splinter in the finger, right?

17 MR. THOMAS: Objection.

18 BY MR. THORNBURGH:

19 Q. There'll be an inflammatory response to that  
20 splinter, right?

21 A. Yes.

22 Q. And there's going to be an inflammatory --

23 MR. THOMAS: Just note my objection to  
24 the question.

25 BY MR. THORNBURGH:

Confidential - Subject to Protective Order

Page 394

1 Q. There's going to be an inflammatory response to  
2 the particles that are loose with inside the woman's  
3 pelvis, right?

4 MR. THOMAS: Object to the form of the  
5 question.

6 THE WITNESS: Yes.

7 BY MR. THORNBURGH:

8 Q. And that inflammatory response can result in  
9 granuloma formation around each one of these particles  
10 contained within the woman's pelvis, right?

11 MR. THOMAS: Object to the form of the  
12 question.

13 THE WITNESS: Yes.

14 BY MR. THORNBURGH:

15 Q. So you're going to have -- essentially, you're  
16 going to end up having little granuloma covered  
17 particles, kind of like little BBs inside the pelvis of  
18 a woman's vagina?

19 MR. THOMAS: Object to form of the  
20 question.

21 THE WITNESS: No, not quite.

22 BY MR. THORNBURGH:

23 Q. Well, they're certainly going to form  
24 granulomas around each one of those particles?

25 MR. THOMAS: Object to form of the

Confidential - Subject to Protective Order

Page 395

1 question.

2 THE WITNESS: They will form the same  
3 kinds of granuloma around the particles as they do  
4 around each individual filament of the mesh.

5 BY MR. THORNBURGH:

6 Q. Right. So you're going to have additional  
7 granuloma formation around those particles?

8 A. Yes.

9 Q. And the body is going to react or is reacting  
10 to each one of those particles within the woman's  
11 vagina?

12 MR. THOMAS: Object to the form of the  
13 question.

14 THE WITNESS: They will be the particles  
15 within the tissues around the mesh.

16 BY MR. THORNBURGH:

17 Q. And, again, you were not asked to conduct a  
18 study looking specifically at the inflammatory response  
19 associated with those particles, correct?

20 A. That's correct.

21 Q. Handing you what's been premarked as Exhibit  
22 2119 a series of e-mails regarding this particle loss  
23 issue.

24 (Document marked for identification as  
25 Deposition Exhibit No. T-2119.)

Confidential - Subject to Protective Order

Page 396

1 BY MR. THORNBURGH:

2 Q. This is November 20 -- if you go down to the  
3 bottom, it's a November 18th, 2005 e-mail from Sungyoon  
4 Rah, right?

5 A. The name sounds familiar.

6 Q. Okay. It's to Jacqueline Flatow, Jendly  
7 Fabrice, Julian Gremion, Daniel Lamont, right?

8 A. That's what it says.

9 Q. With a CC to Chris Vailhe, right?

10 A. Yes.

11 Q. And Manuel Castro.

12 Any of those individuals within the preclinical  
13 department?

14 A. I think Jacqueline Flatow was in the surgical  
15 functionality area.

16 Q. And Sunny Rah, who is operations integration, a  
17 division of Ethicon, Incorporated and Johnson & Johnson  
18 company writes to this team of folks, "I have great  
19 news," and the subject line is "great news for TVT  
20 laser cut mesh." The Bates number for this Exhibit is  
21 00301741.

22 I have great news. I met with Traci Gorky, Dan  
23 Smith, Quentin Manley and made tremendous progress in  
24 the last day. Traci Gorky will be following up with  
25 Gene Kammerer related to some additional testing



Confidential - Subject to Protective Order

Page 397

1 requested to Jackie. Based on several discussions with  
2 Research & Technology Development and Product  
3 Development organization, particle loss, elongation  
4 curve and flexural rigidity data are, in capital  
5 letters, not required for DVer work. They have  
6 specifically stated that these are not CTQs. In  
7 return, this means that will not require Design  
8 Verification activities related to particle loss,  
9 elongation curve, flexural rigidity!!!

10 So instead of going out and studying this  
11 issue, particle loss issue, fraying issue, the  
12 elongation curve, flexural rigidity issues, Sunny Rah  
13 is celebrating the fact that it's been decided not to  
14 undergo additional testing of the mesh, right?

15 A. Well, I was not part of this e-mail string,  
16 although I was at Ethicon at the time, I don't know  
17 about this discussion. It's really outside my area of  
18 preclinical expertise.

19 Q. Right. But you could have -- you could have  
20 been involved in this discussion. You testified  
21 earlier that you were involved in the discussion about  
22 particle loss and fraying.

23 Do you remember that testimony?

24 A. Yes.

25 Q. And so this is a discussion about that issue

Confidential - Subject to Protective Order

Page 398

1 that you were involved with from a preclinical  
2 standpoint, and they're celebrating the fact that  
3 they're not going to conduct additional design  
4 verification activities or testing of the product,  
5 right?

6 MR. THOMAS: Object to the form of the  
7 question.

8 THE WITNESS: I can read the e-mail.

9 BY MR. THORNBURGH:

10 Q. And so that's what the e-mail would appear to  
11 say, right?

12 MR. THOMAS: Object to the form of the  
13 question.

14 THE WITNESS: Yes.

15 BY MR. THORNBURGH:

16 Q. And then Chris Vailhe writes back, Sunny, I am  
17 very surprised at this comment. Particle loss,  
18 elongation curve and flexural rigidity data are not  
19 required for DVer, design verification, work because  
20 they are not CTQs. Particle loss is the reason why TVT  
21 wants to use laser cut mesh, to eliminate particle loss  
22 (which is critical to quality).

23 I agree on the approach of the team to limit  
24 the testing in these area since the report on  
25 ultrasonic cut mesh from Gene already provides a lot of

Confidential - Subject to Protective Order

Page 399

1 information that can be used for rationale not to test  
2 the laser cut mesh. I have the impression that  
3 particle loss, elongation curve and flexural rigidity  
4 are very important CTQs. Right? You understand what  
5 CTQ means?

6 A. Critical to quality.

7 Q. Critical to quality. And yet there is a  
8 decision being made not to test it. So let's forego  
9 critical issues to quality so that we -- and not test a  
10 product that's being permanently implanted in the  
11 pelvis of women, right?

12 MR. THOMAS: Object to the form of the  
13 question.

14 THE WITNESS: I don't know the context  
15 of this e-mail string.

16 BY MR. THORNBURGH:

17 Q. But that's what this e-mail string would  
18 suggest, right?

19 MR. THOMAS: Object to the form of the  
20 question.

21 THE WITNESS: I was not part of this  
22 e-mail string. I don't know the context of it, and it  
23 would be inappropriate for me to comment on areas of  
24 expertise outside my own area of expertise.

25 BY MR. THORNBURGH:

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Page 400

1 Q. You're a preclinical person, right?

2 A. That's a big bucket.

3 Q. Well, you can test animals. You can test  
4 inflammatory response to particles within animals,  
5 can't you?

6 A. I could.

7 Q. But you were never asked by anybody at Ethicon  
8 to do that, right?

9 MR. THOMAS: Object to the form of the  
10 question.

11 THE WITNESS: Not to my recollection.

12 BY MR. THORNBURGH:

13 Q. And you've never volunteered, knowing that this  
14 was an issue, you never personally volunteered to  
15 undertake that task of doing a simple 21-day back end  
16 or rat back study to determine the inflammatory  
17 response from these particles, right?

18 MR. THOMAS: Object to the form of the  
19 question.

20 THE WITNESS: I would have said that  
21 it's not necessary and would have pointed to the 28-day  
22 study where the TVT mesh and any associated particles  
23 were implanted, and the tissue reaction was mild and  
24 acceptable.

25 BY MR. THORNBURGH:

Confidential - Subject to Protective Order

Page 401

1 Q. Another justification, right?

2 MR. THOMAS: Object to the form of the  
3 question.

4 THE WITNESS: That's a result. That  
5 would be a result.

6 BY MR. THORNBURGH:

7 Q. Another excuse not to conduct additional  
8 testing, right?

9 MR. THOMAS: Objection.

10 THE WITNESS: I don't agree.

11 BY MR. THORNBURGH:

12 Q. Daniel Lamont says, I am glad I was not the  
13 only one that had a problem with this e-mail. Perhaps  
14 Sunny will actually sit down with the team and define  
15 requirements instead of letting management do so.

16 Was management getting in the way of doing this  
17 critical to quality testing of the products that were  
18 being implanted in women's vaginas all across the world  
19 and all across the United States?

20 MR. THOMAS: Object to the form of the  
21 question.

22 THE WITNESS: I can't comment on that.  
23 I don't know the context of the e-mail stream or any of  
24 the background information.

25 BY MR. THORNBURGH:

Confidential - Subject to Protective Order

Page 402

1 Q. Again, you weren't asked to undergo -- to  
2 undertake a task of making sure that the critical --  
3 that the critical to quality testing was undertaken,  
4 right?

5 A. That was not my area of expertise.

6 Q. Your area of expertise was preclinical, right?

7 A. Yes.

8 Q. You were kind of the person in preclinical that  
9 would often issue justification memos about why testing  
10 wasn't needed, right?

11 MR. THOMAS: Object to the form of the  
12 question.

13 THE WITNESS: If they were appropriate,  
14 yes.

15 (Document marked for identification as  
16 Deposition Exhibit No. 2120.)

17 BY MR. THORNBURGH:

18 Q. I'm going to hand you what's been marked  
19 Exhibit 2120, another e-mail regarding particle loss  
20 issue.

21 So in this e-mail dated February 15, 2006 --

22 MR. THOMAS: May I have a copy, please?

23 MR. THORNBURGH: I'm sorry, Dave. I  
24 didn't mean that.

25 BY MR. THORNBURGH:

Confidential - Subject to Protective Order

Page 403

1 Q. In this e-mail dated February 15, 2006, Sunny  
2 Rah says, hey Jackie, please provide me DVer, or design  
3 verification, protocol for particle loss. I'm  
4 wondering if we may be able to perform particle loss on  
5 only at the lower or low power setting runs rather than  
6 for both low and high settings.

7 Remember yesterday when we talked about the  
8 importance of looking at worst case scenario.

9 Do you remember that discussion?

10 A. Yes.

11 Q. And you agreed with me yesterday that it's  
12 important to look at worst case scenario?

13 A. Yes.

14 Q. And in this case Sunny Rah is suggesting that  
15 we do a low power setting test on particle loss rather  
16 than the low and high, right?

17 A. I see that, but I don't know what that means.  
18 I don't know which one is worst case, the higher or the  
19 lower.

20 Q. "Of course, we will need to provide the  
21 justification memo stating that lower settings will  
22 create less besides and lower particles."

23 That's what she writes, right?

24 MR. THOMAS: Object to form of the  
25 question.

Confidential - Subject to Protective Order

Page 404

1 BY MR. THORNBURGH:

2 Q. Or Sunny Rah writes, right?

3 A. I can read this memo, yes.

4 Q. And then Jacqueline Flatow or Flatow responds,  
5 I'd like to repeat particle loss DVer, design  
6 verification, on nominal parts - the fewer  
7 justification memos we have, the better. The fewer  
8 evidence there is that we're not -- that we're electing  
9 not to undergo testing of our product, the better?

10 MR. THOMAS: Is that a question?

11 MR. THORNBURGH: Yeah.

12 MR. THOMAS: Object to the form of the  
13 question.

14 BY MR. THORNBURGH:

15 Q. Here we go, you're the guy who is responsible  
16 in part in drafting these justification letters, and  
17 Jacqueline Flatow says, the fewer justification memos  
18 we have, the better, right? That's what she says?

19 MR. THOMAS: Object to the form of the  
20 question.

21 THE WITNESS: That's what she says.

22 BY MR. THORNBURGH:

23 Q. And we saw yesterday when we looked at the  
24 10993 studies that you didn't conduct any of those  
25 studies. You wrote justification memos or



Confidential - Subject to Protective Order

Page 405

1 justification reasons for not undergoing the certain  
2 10993 testing, correct?

3 A. That's correct.

4 MR. THOMAS: Object to the form of the  
5 question.

6 BY MR. THORNBURGH:

7 Q. Going to hand you what's been marked as 2121,  
8 ETH.MESH.01221055, the Pariente study.

9 (Document marked for identification as  
10 Deposition Exhibit No. T-2121.)

11 BY MR. THORNBURGH:

12 Q. Okay. So, as you can see from this study, it's  
13 called "An independent biomechanical evaluation of  
14 commercially available suburethral slings," and the  
15 author is J-L Pariente.

16 You see that?

17 A. Yes.

18 Q. And it's from the -- I'm going to try, I'm  
19 going to butcher it, but it's from the Centre  
20 d'Innovations Technologiques Biomatériaux, Hopital  
21 Pellegrin and so forth, right?

22 A. Yes.

23 Q. You see that, in France?

24 A. I see that.

25 MR. THOMAS: Counsel, do you have a date

Confidential - Subject to Protective Order

Page 406

1 for this study?

2 MR. THORNBURGH: I do. Well, I can tell  
3 you, I can represent to you that it was July of 2005.

4 BY MR. THORNBURGH:

5 Q. Okay. So this is a study that looked at  
6 particle loss in a number of different suburethral  
7 slings, including TVT, right?

8 A. I have not had a chance to read this paper.  
9 This is really outside my area of expertise. It's all  
10 about biomechanical testing, and it looks like in a  
11 clinical setting.

12 Q. Right. Well, let's look at this together, and  
13 I'll walk you through it, okay. Under "Abstract" it  
14 says, many questions remain unanswered about the  
15 physical properties of suburethral slings. We report a  
16 laboratory based study that compared in vitro  
17 biomechanical characteristics of six slings used for  
18 stress urinary incontinence: TVT, which is  
19 manufactured by Ethicon, IVS, Uretex, I-stop and  
20 Uratape.

21 You see that?

22 A. Yes.

23 Q. It says, "each sling was found to have quite  
24 different mechanical properties, varying from soft to  
25 hard tapes, and elastic to very stiff tapes."

Confidential - Subject to Protective Order

Page 407

1           So this is discussing a mechanical properties  
2 test of a number of suburethral slings including TVT,  
3 right?

4       A.       Yes.

5       Q.       And it goes on to say, "an assessment was made  
6 of the amount of material shed by each tape during the  
7 testing procedure. This may have relevance to the  
8 clinical situation, where particles shed during  
9 surgical manipulation, may end up in the surrounding  
10 soft tissue with unpredictable impact on future  
11 success."

12           That's what Dr. Pariente writes, right?

13       A.       Yes.

14       Q.       So what do you think the percentage of particle  
15 loss was with the TVT tape compared to the other tapes?

16       A.       I don't know.

17       Q.       Well, if you turn with me to -- turn with me to  
18 the second page, it says -- see the section beginning  
19 with to evaluate the shedding particles?

20       A.       Yes.

21       Q.       To evaluate the shedding of particles, each  
22 sample was weighed before and after a soft procedure,  
23 and the values range from 0 to 8.5 percent of initial  
24 weight. During surgical use, these particles were  
25 released in soft tissue and is not possible to know

Confidential - Subject to Protective Order

Page 408

1 where they go.

2 And it reports that TVTs particle loss was the  
3 highest on the next page with particle loss of -- which  
4 would be the particle loss of 8.5, as you can see in  
5 Table 2 on the last page, Bates Number 1058.

6 You see that?

7 A. Yes.

8 Q. TVT of all of the -- and if you can go ahead  
9 and blow that up -- TVT, Ethicon's product, the product  
10 that you were in charge of the bio -- the preclinical  
11 compatibility testing for, this product had the highest  
12 particle loss of 8.5%, correct?

13 MR. THOMAS: Object to the form of the  
14 question.

15 THE WITNESS: I see that.

16 BY MR. THORNBURGH:

17 Q. Okay. And these doctors were saying this could  
18 have an impact clinically on patient outcomes, right?

19 MR. THOMAS: Object to the form of the  
20 question.

21 THE WITNESS: I don't see that written,  
22 but if it is, then that's the case.

23 BY MR. THORNBURGH:

24 Q. If you go back to Page 1 it says this may have  
25 relevance to the clinical situation?

Confidential - Subject to Protective Order

Page 409

1 A. I see it.

2 Q. With particle loss being shed during surgical  
3 manipulation of the slings, right?

4 A. Yes.

5 Q. And so the reported 8.5 particle loss for TVT,  
6 which, according to the Pariente, could impact the  
7 outcome for patients, right?

8 MR. THOMAS: Object to form of the  
9 question.

10 THE WITNESS: That's what this person is  
11 saying.

12 BY MR. THORNBURGH:

13 Q. One of the ways to understand what that impact  
14 to humans may be would be to look at it in animals,  
15 right?

16 A. Yes.

17 Q. And what you could have done is you could have  
18 cut open the back end of a rat, took 8.5% of the mesh  
19 in particle form, put it in the back of the rat or  
20 whatever animal model you choose to use and see what  
21 the reaction would be both in terms of tissue reaction,  
22 inflammatory response and migration of the particles,  
23 right?

24 MR. THOMAS: Object to the form of the  
25 question.

Confidential - Subject to Protective Order

Page 410

1 THE WITNESS: That would not be relevant  
2 to the final product.

3 BY MR. THORNBURGH:

4 Q. The final product, as we saw from all these  
5 complaints, had the same issue, had particle loss  
6 occurring during the implantation in patients, right?

7 MR. THOMAS: Object to the form of the  
8 question.

9 BY MR. THORNBURGH:

10 Q. We saw all the complaints, right. You saw  
11 Dr. Eberhard saying it's embarrassing, this tape is  
12 terrible, particles are coming off of the tape, right?

13 A. I recall his --

14 MR. THOMAS: Object to form of the  
15 question.

16 THE WITNESS: I recall his memo.

17 BY MR. THORNBURGH:

18 Q. He's one of the doctors in the field. He's an  
19 actual MD who is actually implanting these devices in  
20 women, and he is saying, Ethicon, you got to change it,  
21 right?

22 MR. THOMAS: Object to the form of the  
23 question.

24 THE WITNESS: That's what he said.

25 BY MR. THORNBURGH:

Confidential - Subject to Protective Order

Page 411

1 Q. And we saw other complaints from other doctors  
2 in the field who are complaining about particle loss  
3 and how it's an issue for them and that it's become  
4 more obvious after the pigmented blue dyes were  
5 incorporated into the mesh, right?

6 MR. THOMAS: Object to the form of the  
7 question.

8 THE WITNESS: What was the question  
9 there?

10 BY MR. THORNBURGH:

11 Q. Yeah, we saw other complaints from other  
12 physicians in the field about particle loss, right?

13 MR. THOMAS: Object to the form of the  
14 question.

15 THE WITNESS: Yes.

16 BY MR. THORNBURGH:

17 Q. And we looked at a discussion within Ethicon of  
18 the potential to study the particle loss issue in their  
19 design verification testing, you remember?

20 A. I don't know the context of that discussion.

21 Q. But you remember seeing that document, right?

22 A. Yes.

23 Q. And a decision was made not to test it.

24 Do you remember that?

25 A. I don't know how that ultimately was resolved.

Confidential - Subject to Protective Order

Page 412

1 Q. Well, I'm going to show you how it was  
2 ultimately resolved, but you remember that discussion?

3 A. Yes, we reviewed that e-mail string.

4 Q. And those were issues that some of the folks  
5 like Dan Lamont thought was important for criminal to  
6 quality issues for the product, right?

7 A. Whatever is in those memos.

8 Q. You remember reading that; that's what those  
9 memos said, right?

10 A. Yes.

11 Q. So now we've got Pariente defining the amount  
12 of particle loss, and for TVT it's 8.5%, according to  
13 this study, right?

14 A. Yes.

15 Q. Going to hand you what's been premarked as  
16 Exhibit 2122, an e-mail string regarding the particle  
17 loss issue and standardization under AFNOR.

18 (Document marked for identification as  
19 Deposition Exhibit No. T-2122.)

20 BY MR. THORNBURGH:

21 Q. Do you know what AFNOR is?

22 A. AFNOR, no.

23 Q. Do you understand that France had a  
24 standardization committee that would standardize  
25 testing and materials which would later be adopted by



Confidential - Subject to Protective Order

Page 413

1 European countries?

2 A. I don't think I -- I don't recall that.

3 Q. Well, let's look at this, so you get some  
4 background, okay. So, again, I'm going to have you  
5 turn -- the Bates number is 03358217, and the subject  
6 is, as you can see on Page 1 on this May 1st, 2006  
7 e-mail, French standard on TVT and meshes.

8 And so if you turn with me to  
9 ETH.MESH.003358222, it's an e-mail from Scott Ciarrocca  
10 to a number of individuals directed to Xavier and  
11 Pascale. It says, looking into finding a way to give  
12 you specifics. It is unfortunately not straightforward  
13 to obtain all this. To be clear, we're talking about  
14 Prolene Gynemesh® Soft, the implantable materials, not  
15 the TVT or Prolift® devices.

16 Actually, let me -- if you go ahead to the very  
17 last page, sorry about that, 8224, the subject is AFNOR  
18 (ISO) Organization - Request.

19 You see that?

20 A. Yes.

21 Q. And it says -- it's an e-mail from Xavier at  
22 Gynecare France saying, over the last few months in our  
23 country we are -- we can observe a clear awareness from  
24 the KOLs and other surgeons in regard to what is or not  
25 a good prosthesis, both for SUI slings and prolapse

Confidential - Subject to Protective Order

Page 414

1 repair.

2 Under the initiative of Gynecare France, we  
3 succeed in convincing our local standards organization  
4 (AFNOR) to set up a commission. Her goal will be to  
5 try to standardize that market in those both areas.  
6 First step will be a local standard and then a European  
7 one.

8 The two co-presidents for that commission will  
9 be Professor Jacquetin.

10 You know who that is, right?

11 A. I've heard of that person.

12 Q. And Professor Haab. Further to our last  
13 meeting with AFNOR guys, we have been requested as  
14 others competitors to provide the following for TVT and  
15 TVT-O as well as TVM Prolift®, initial testing  
16 completed before releasing the product on the market  
17 (material characterization, et cetera), applicable  
18 standards for previous point (clinicals, materials,  
19 test methods), the way we as manufacturer did evaluate  
20 the products for preclinical side as well as clinical  
21 side (literature analysis, animal trials, human  
22 investigations).

23 So this is talking about a need -- talking  
24 about a group called AFNOR, which is a French  
25 standardization organization, which is requesting

Confidential - Subject to Protective Order

Page 415

1 information from manufacturers, right?

2 A. Yes.

3 Q. And one of the things being requested is  
4 preclinical information, right?

5 A. Yes.

6 Q. If you go to Bates Number 8219, Dr. Fournier or  
7 Herve Fournier says, as you probably know, AFNOR  
8 (French standardization organization) prepares a  
9 standard on SUI tapes and prolapse repair meshes  
10 implanted by vaginal ways. Manufacturers, surgeons,  
11 KOLs and AFSSAPS are gathered in a TF S92B, which is  
12 split in two working groups to write the draft of the  
13 standard which is scheduled to be to CEN in the next  
14 forthcoming years.

15 You see that?

16 A. Yes.

17 Q. Kind of similar to the work you did, the  
18 working group that you did for ISO, there is a French  
19 standardization organization that does similar  
20 standardization of testing, right?

21 A. That's correct.

22 Q. Then if you turn the page, so there's some  
23 information about the people that will be involved in  
24 these working groups, couple of those folks as you can  
25 see are from Ethicon, and if you go to Bates Number

Confidential - Subject to Protective Order

Page 416

1 8221 it says, I received the homework from our  
2 colleagues of the WG1 last March 21st in French.  
3 Please find those ones in the zip file attached, and  
4 there's a zip file that is attached. It says which one  
5 includes as follows, suggestions on Paragraph 4 of the  
6 standard, and it goes on to say below that suggestions  
7 on Paragraph 5.1, 5.2 of the standard on fraying.

8 You see that?

9 A. Yes.

10 Q. Okay. So one of the issues that is being  
11 identified as part of the standardization processes of  
12 AFNOR is the fraying potentiation of SUI slings, right?

13 MR. THOMAS: Object to the form of the  
14 question.

15 THE WITNESS: Yes.

16 BY MR. THORNBURGH:

17 Q. And if you go to page -- the first page, it's  
18 got 5.2.2 particle release fraying section defined. It  
19 says, describes a method of measuring of particles  
20 which may be released from the implant while implanted  
21 in the body. Generally, when we talk about fraying as  
22 associated with urethral slings and pelvic floor  
23 support materials made from meshes, we are describing  
24 loss of pieces of the device as it is manipulated  
25 during insertion. Our tests are done on weight loss

Confidential - Subject to Protective Order

Page 417

1 basis. We do not count particles or observe particle  
2 size. Briefly, the mesh is weighed, then stretched to  
3 a specific tension or percentage elongation then  
4 weighed again, and the difference in weight is reported  
5 as percentage of particle loss.

6 That makes sense, doesn't it?

7 A. Yes.

8 Q. It says, and this looks like to be the comments  
9 from Gene Kammerer regarding this particle loss  
10 standardization that's being discussed at AFNOR, right?

11 MR. THOMAS: Object to the form of the  
12 question.

13 THE WITNESS: I can read the e-mail.  
14 I'm not part of this stream. This is outside my area  
15 of expertise. I can simply read it as a scientist and  
16 offer up whether or not what you're reading is what's  
17 in the text.

18 BY MR. THORNBURGH:

19 Q. Right. What I'm reading is what's in the text,  
20 right?

21 A. It looks that way.

22 Q. And I'm going to show you how you're tied to  
23 this. We're going to go further and further as we get  
24 through today, and you're going to see your connection,  
25 but you certainly were a part of this discussion while

Confidential - Subject to Protective Order

Page 418

1 you were at Ethicon.

2 You recalled that previously, right?

3 A. Not part of this discussion.

4 Q. You were a part of the particle loss  
5 discussion, the fraying discussion?

6 A. I was part of some of the discussion around  
7 particle loss.

8 Q. Right, right. And let me guess, you came up  
9 for justification not to do testing?

10 MR. THOMAS: Object to the form of the  
11 question.

12 THE WITNESS: No, I did not.

13 BY MR. THORNBURGH:

14 Q. We'll see what the record shows later on, but  
15 it goes on, we have no specific specification or  
16 limitation. The data is collected for information  
17 purposes only. It would not be proper to add a  
18 specification about -- it would not be proper to add a  
19 specification amount of acceptable loss. For example,  
20 a mesh weighing 2 grams is inserted into the body. It  
21 is determined that during insertion 0.4% of the mesh is  
22 dislodged. So 0.008 grams of the mesh is in the body  
23 but not attached to the main structure.

24 Well, we know from the Pariente study that what  
25 Pariente found was 8.5% of TVT mesh is lost during the

Confidential - Subject to Protective Order

Page 419

1 implantation process?

2 MR. THOMAS: Objection.

3 BY MR. THORNBURGH:

4 Q. Based on the study that was done by Pariente?

5 MR. THOMAS: Object to form of the  
6 question.

7 BY MR. THORNBURGH

8 Q. Right?

9 A. That's correct.

10 Q. And so it goes on to say I think it means  
11 nothing from safety, clinical or functional aspect of  
12 the product.

13 They didn't even ask you to test it, right?

14 MR. THOMAS: Object to the form of the  
15 question.

16 THE WITNESS: Again, I don't know the  
17 context of this discussion. I was not part of it.  
18 This is project team related work that was done  
19 outside. I was not on the project team.

20 BY MR. THORNBURGH:

21 Q. You know who Gene Kammerer is, right?

22 A. Yes.

23 Q. He's not an MD, right?

24 A. No.

25 Q. In fact, the highest level of education that

Confidential - Subject to Protective Order

Page 420

1 Gene Kammerer has is an Associate's degree, correct?

2 A. I don't know that.

3 Q. I'll represent to you that during his  
4 deposition, he informed me that the highest level of  
5 education was an Associate's degree, okay?

6 A. Okay.

7 Q. All right. So you would expect people that  
8 were part of the clinical physicians, MDs to be calling  
9 the shots on what it means clinically to the safety of  
10 patients this particle loss and fraying issue, right?

11 MR. THOMAS: Object to the form of the  
12 question.

13 THE WITNESS: The best I can tell is  
14 Gene is making reference to the fact that if you  
15 present a particle loss in percentage, it doesn't mean  
16 much, if you don't know what the weight of the starting  
17 device is. I think that's what he's talking about,  
18 but, again, I don't know of a context. It's out of my  
19 area. I can simply read this as a scientist and offer  
20 a comment.

21 BY MR. THORNBURGH:

22 Q. But that wasn't my question. Here we've got  
23 Gene Kammerer, who is in the research and design  
24 department at Ethicon, who has a Associate's degree  
25 saying, I don't think it means anything about safety,



Confidential - Subject to Protective Order

Page 421

1 right?

2 A. They say in the percentage representation means  
3 nothing. It means nothing in a number of different  
4 ways.

5 Q. He says I think it means nothing from a safety,  
6 clinical or functional aspect of the product.

7 What do you think he means by safety?

8 MR. THOMAS: Object to the form of the  
9 question.

10 THE WITNESS: He's talking about the use  
11 of percentage, and using percentage loss doesn't mean  
12 anything, unless you know the weight of the initial  
13 product.

14 BY MR. THORNBURGH:

15 Q. But as you testified earlier, you're a Ph.D.  
16 who you are responsible or were responsible to Ethicon  
17 for testing products on animals, that each one of those  
18 particles will be a foreign body that the body will  
19 react to, and there will be an inflammatory response,  
20 right?

21 MR. THOMAS: Object to the form of the  
22 question.

23 THE WITNESS: I can't add anything to  
24 what I've already spoke.

25 BY MR. THORNBURGH:

Confidential - Subject to Protective Order

Page 422

1 Q. Preclinically in animals, you can -- I  
2 understand you've said it before, I'm asking you to say  
3 it again, in animals when you have this foreign body  
4 and you have additional foreign bodies from the  
5 particles that are lost during implantation of the  
6 device, each one of those particles as well as the  
7 actual full product mesh inserted in the patient or in  
8 an animal is going to trigger a foreign body response,  
9 right?

10 MR. THOMAS: Object to the form of the  
11 question.

12 THE WITNESS: Yes.

13 BY MR. THORNBURGH:

14 Q. An inflammatory response, correct?

15 A. Yes.

16 Q. Which will result in granuloma formation over  
17 each one of those particles and over the mesh?

18 MR. THOMAS: Object to the form of the  
19 question.

20 THE WITNESS: The inflammatory reaction  
21 is a granulomatous reaction.

22 BY MR. THORNBURGH:

23 Q. Right. So but Gene Kammerer says, well,  
24 therefore, the particle loss test is not relevant,  
25 unless it can be identified that the material which

Confidential - Subject to Protective Order

Page 423

1 frays has some impact on the safety, clinical outcome  
2 or functionality of the product.

3 A good place to start would have been with you?

4 MR. THOMAS: Is that a question?

5 MR. THORNBURGH: Yeah.

6 MR. THOMAS: Object to the form of the  
7 question.

8 THE WITNESS: I can't -- I can't speak  
9 for Gene. Whatever he says is what he said.

10 BY MR. THORNBURGH:

11 Q. I'm not asking you to speak for Gene. I'm  
12 asking you to speak for yourself.

13 A. And the question is?

14 Q. A good place to start to look at safety from a  
15 preclinical standpoint to look at the risk that could  
16 be associated with the particle loss or fraying issue  
17 would have been to go to you and say test this, test  
18 this issue?

19 MR. THOMAS: Object to the form of the  
20 question.

21 BY MR. THORNBURGH:

22 Q. That would have been a good place to start,  
23 you, right?

24 A. They could have done that.

25 Q. They didn't, right?

Confidential - Subject to Protective Order

Page 424

1 A. I don't recall that we didn't have verbal  
2 discussions about that.

3 Q. But they could have asked you to go do a little  
4 test, to take a rat, cut open its back or cut open the  
5 back end of it, take this, as Dan Smith described, this  
6 blue shit that's falling off of the mesh, and put it in  
7 the animal model to see what the reaction might be,  
8 right?

9 MR. THOMAS: Object to the form of the  
10 question.

11 THE WITNESS: We did such a relevance  
12 study implanting TVT mesh and any associated particles  
13 in the 28-day rat study.

14 BY MR. THORNBURGH:

15 Q. Twenty-eight day rat study.

16 My question to you is did you actually take the  
17 mesh and do this -- have the people like Gene Kammerer  
18 run a test and get the particles to fall off and take  
19 those particles, the blue particles, put it in the back  
20 end of a rat to see what the inflammatory response will  
21 be to the particles?

22 MR. THOMAS: Object to the form of the  
23 question. You are continuing to argue with the  
24 witness, just ask him questions.

25 MR. THORNBURGH: I'm not arguing with

Confidential - Subject to Protective Order

Page 425

1 him.

2 MR. THOMAS: Yes, you are.

3 MR. THORNBURGH: No, I'm not.

4 BY MR. THORNBURGH:

5 Q. Did you ever do that study?

6 A. I think I've answered that a half a dozen  
7 times, and the answer was no.

8 (Document marked for identification as  
9 Deposition Exhibit No. T-2123.)

10 BY MR. THORNBURGH:

11 Q. Handing you what's been premarked as Exhibit  
12 2123, an e-mail from Gene Kammerer regarding slings and  
13 as you'll see, it has to do with particle loss, and the  
14 AFNOR standards as well as the Pariente study?

15 MR. THOMAS: May I have one, please.

16 MR. THORNBURGH: Of course you may,  
17 Dave.

18 BY MR. THORNBURGH:

19 Q. As you'll see in here, as we get through the  
20 discussion, AFNOR was considering setting a limit for  
21 particle loss at -- I'm sorry at 5%, okay. So that  
22 would obviously be a problem for Ethicon if the  
23 particle loss for TVT was 8.5%, right?

24 MR. THOMAS: Object to the form of the  
25 question.

Confidential - Subject to Protective Order

Page 426

1 THE WITNESS: Yes.

2 BY MR. THORNBURGH:

3 Q. So let's see what Gene Kammerer recommends.

4 Why don't you just take a moment, look at that  
5 document, because I'm going to talk to you about it at  
6 length. ETH.MESH Number 01221024.

7 MR. THOMAS: Could we go off the record  
8 briefly.

9 MR. THORNBURGH: Yeah.

10 THE VIDEOGRAPHER: Going off the record.  
11 The time is 11:06 a.m.

12 (Brief recess.)

13 THE VIDEOGRAPHER: Back on the record,  
14 the time is 11:10 a.m.

15 THE WITNESS: Shall I continue to read  
16 through?

17 BY MR. THORNBURGH:

18 Q. I'm going to just -- I'm not going to spend  
19 that much time on this, actually, just to try to save  
20 us some time.

21 A. Good.

22 Q. So I'll try to point out for you -- you know,  
23 try to walk you through this document.

24 A. Okay.

25 Q. So, again, it's Gene Kammerer, May 4th, 2006,

Confidential - Subject to Protective Order

Page 427

1 and it's a discussion of the Pariente findings as well  
2 as the standards being set by AFNOR of 5% particle loss  
3 is the sort of cutoff limit for meshes, okay?

4 A. Okay.

5 Q. And it talks about the study that was done and  
6 says that during the study, you look with me, you'll  
7 see on the -- six lines down from the top where it  
8 starts with in the test.

9 A. Yes.

10 Q. It says, in this test the strips are pulled ten  
11 times up to a load of 25 Newtons, 5.6 pounds. The  
12 difference in weight before and after is determined.  
13 The recommended limit for acceptance is less than 5% of  
14 the sample weight should fall off.

15 That's what we were talking about, and I'll  
16 show you later on how 5% is the cutoff that AFNOR was  
17 considering for particle loss. It says, here are a few  
18 objections, so Kammerer is saying I've got objections  
19 to this test.

20 You see that, right?

21 A. Yes.

22 Q. And he lays those out, the load cell on the  
23 Instron test is a maximum of 500 Newtons, and the test  
24 is done at 25 Newtons. He says it should be at 100 to  
25 150 Newtons.

Confidential - Subject to Protective Order

Page 428

1           You see that?

2    A.       Yes.

3    Q.       So he is saying the test is too rigorous. It  
4       should be -- we should test it at less Newtons, right?

5                   MR. THOMAS: Object to the form of the  
6       question.

7                   THE WITNESS: No. Again, I'm not a  
8       biomechanical engineer. What the sentence is saying is  
9       that he's saying that he is trying to test or set the  
10      load cell at 500 Newtons is insufficiently sensitive to  
11      get good resolution and accuracy at just 25 Newtons.  
12      He is saying you ought to make the test more sensitive  
13      by decreasing the load cell to something more in the  
14      range of 25 Newtons.

15   BY MR. THORNBURGH:

16   Q.       Okay. Well, we'll see what he goes on to say,  
17      okay, because he goes to say, the sample is stretched  
18      ten times, this is way too many times to stretch. One  
19      time should be sufficient. One time. So remember how  
20      we talked about earlier how the worst case scenario for  
21      a patient is important testing to do.

22                   Do you remember that discussion?

23                   MR. THOMAS: Objection.

24                   THE WITNESS: Yes.

25   BY MR. THORNBURGH:



Confidential - Subject to Protective Order

Page 429

1 Q. So here they're talking about the test pull it  
2 ten times and Kammerer is saying, no, let's just pull  
3 it one time.

4 You see that?

5 MR. THOMAS: Object to the form of the  
6 question. I think you're arguing with the witness  
7 again.

8 MR. THORNBURGH: Dave, I'm not arguing  
9 with the witness. I do get excited, but I'm not trying  
10 to argue with the witness.

11 THE WITNESS: I see what he's saying. I  
12 can't speak to his rationale or understanding of the  
13 details of his thinking. I just see these sentences  
14 and they're as you state them.

15 BY MR. THORNBURGH:

16 Q. So what he's saying is let's not pull it ten  
17 times, let's pull it one time, right?

18 MR. THOMAS: Object to the form of the  
19 question.

20 BY MR. THORNBURGH

21 Q. Right?

22 A. He says one time should be sufficient.

23 Q. Because, remember, if the particle loss is 8.5,  
24 it doesn't meet the AFNOR standards at 5%, right?

25 MR. THOMAS: Object to form of the

Confidential - Subject to Protective Order

Page 430

1 question.

2 THE WITNESS: I don't know that the 8.5%  
3 from this Pariente study was done under these load cell  
4 conditions.

5 BY MR. THORNBURGH:

6 Q. But assuming with me that AFNOR standard is 5%  
7 for the maximum amount of particle loss, if it's 8.5%  
8 or anywhere greater than 5%, that's a problem for  
9 Ethicon?

10 MR. THOMAS: Object to the form of the  
11 question.

12 THE WITNESS: It would not.

13 BY MR. THORNBURGH:

14 Q. It would not meet the standard?

15 A. If this standard was ever finalized. I mean,  
16 the discussion about how to do a standard takes a great  
17 deal of time. It looks at input from a wide range of  
18 people, and there's many times this is very standard.  
19 I don't know if this is where they landed with the  
20 standard or not. I don't know that.

21 MR. THOMAS: Note my objection to this.  
22 You continue to ask Dr. Barbolt about documents he's  
23 never seen before and asking him to give his opinions  
24 on things he had no involvement with.

25 MR. THORNBURGH: He did have

Confidential - Subject to Protective Order

Page 431

1 involvement.

2 MR. THOMAS: I think it's a waste of  
3 time.

4 MR. THORNBURGH: He did have  
5 involvement, and we'll get to additional documents that  
6 showed his involvement. He's already testified that he  
7 was involved in discussions.

8 MR. THOMAS: I don't want to argue with  
9 you about it. I just want to state my objection for  
10 the record.

11 BY MR. THORNBURGH:

12 Q. So let's move on.

13 The maximum number force is pulled to 25  
14 Newtons.

15 You see that?

16 A. Yes.

17 Q. So the maximum force it is pulled to is 25  
18 Newtons for the TVT tape at 1.1 centimeters wide, this  
19 equals about 30% stretch.

20 So I don't have an issue with the percent  
21 stretch, but to do it ten times is unreasonable.

22 You see that? That's what he writes?

23 A. Yes, that's his view. That's what he writes.

24 Q. Instead he's saying it should be done one time,  
25 right?

Confidential - Subject to Protective Order

Page 432

1 A. That's what he suggests.

2 Q. When the tape is in place and is stretched by  
3 the patient during everyday movement, Dr. Lin in his  
4 study published in the Journal of Urology, March 2005  
5 found that the force applied by the downward movement  
6 of the bladder and urethra would be a maximum of  
7 100 grams or one Newton. That's what it says --

8 A. Again, I'm not a biomechanical engineer. These  
9 numbers really don't mean a lot to me.

10 Q. I understand, but I'm walking you through it,  
11 and you're going to see why it matters. The reason why  
12 it -- and, as we've already looked at, the reason why  
13 it matters is if there's particle loss, there's going  
14 to be an inflammatory response with inside an animal  
15 and with inside a human?

16 A. I think we've already established that.

17 Q. Right. So instead of looking at the worst case  
18 scenario, as you will see, which was often the case at  
19 Ethicon, what we see here is protocol for testing that  
20 would create less particle loss.

21 MR. THOMAS: Object to the form of the  
22 question.

23 THE WITNESS: I can't comment on their  
24 motives. That was not part of this discussion or this  
25 e-mail stream. This was an area outside of my

Confidential - Subject to Protective Order

Page 433

1 preclinical area of expertise.

2 BY MR. THORNBURGH:

3 Q. If you go down to in the report by  
4 Dr. Pariente, the TVT tape lost 85% of its weight under  
5 these test conditions.

6 Did I read that accurate?

7 MR. THOMAS: No, you didn't.

8 THE WITNESS: No.

9 BY MR. THORNBURGH:

10 Q. "In the report by Dr. Pariente the TVT tape  
11 lost 8.5% of its weight under these test conditions."

12 A. That's correct.

13 Q. "The maximum limit for weight loss is arbitrary  
14 at 5%. No proven rationale is provided for that  
15 limit."

16 In his study only TVT would fail, in the  
17 Pariente study. Remember when we looked at it, TVT had  
18 the highest particle loss percentage at 8.5%, remember  
19 that?

20 MR. THOMAS: Object to the form of the  
21 question.

22 THE WITNESS: Yes, I remember it.

23 BY MR. THORNBURGH:

24 Q. So and the other ones were less than 5%, so all  
25 of the other TVT or all of the other midurethral slings

Confidential - Subject to Protective Order

Page 434

1 on the market, according to that study, would have  
2 passed with the exception of Ethicon's TVT?

3 A. No, that's not --

4 MR. THOMAS: Object to the form of the  
5 question.

6 THE WITNESS: That's not correct. The  
7 Pariente study shows the SPARC device losing 5.4%.

8 BY MR. THORNBURGH:

9 Q. So the SPARC may fail at 5.4%, and so would the  
10 TVT, right?

11 A. Yes.

12 Q. So, anyway, he goes on to say in summary the  
13 test is far too violent or forceful to provide accurate  
14 information. The limit is arbitrary. The test does  
15 not reflect true operation -- operative conditions,  
16 right? That's what his summary was in this document,  
17 right?

18 MR. THOMAS: Object to the form of the  
19 question.

20 THE WITNESS: That's what it looks like.

21 BY MR. THORNBURGH:

22 Q. Hand you what's been marked as 2124, an e-mail  
23 dated May 9th, 2006.

24 (Document marked for identification as  
25 Deposition Exhibit No. T-2124.)

Confidential - Subject to Protective Order

Page 435

1 BY MR. THORNBURGH

2 Q. And if you go down to the bottom of the  
3 first -- the front page it says, Jackie, I need some --  
4 this is, again, from Gene Kammerer May 9th, 2006, "I  
5 need some clarification on the particle loss test.  
6 France is trying to set new standards for the TVT like  
7 products. Particle loss is one of the standards. They  
8 have a test method which shows 8.5% loss for TVT. I am  
9 challenging their methods as too vigorous."

10 You see that?

11 A. Yes.

12 Q. They have since backed off of the roughness of  
13 the test, but TVT still has very high percentage. It  
14 will fail the test if the test is expected as stands  
15 and we will not be able to sell in France next year.

16 I read that correctly, right?

17 MR. THOMAS: Object to the form of the  
18 question.

19 THE WITNESS: Yeah, that's what it says.

20 BY MR. THORNBURGH:

21 Q. Is there any discussion here from Gene Kammerer  
22 saying, you know what, we ought to take this particle  
23 loss issue seriously, because what we care about is not  
24 selling the product in France, what we care about is  
25 patient safety. So what we should do is send over a

Confidential - Subject to Protective Order

Page 436

1 request to Dr. Barbolt and say, Dr. Barbolt, what does  
2 this mean clinically, at least preclinically in  
3 animals, as it relates to the safety.

4 MR. THOMAS: Object to the form of the  
5 question. You're arguing with him. You're being very  
6 disrespectful of the witness.

7 MR. THORNBURGH: I'm not arguing with  
8 him.

9 MR. THOMAS: I think you are, and the  
10 transcript will bear it out. We'll figure that out  
11 some day.

12 THE WITNESS: I can't speak for what  
13 Gene should have or shouldn't have done.

14 BY MR. THORNBURGH:

15 Q. That wasn't my question. My question was Bates  
16 number is 01219629. So my question was is there any  
17 discussion here from Gene Kammerer saying, you know  
18 what, we ought to take this particle loss issue  
19 seriously because what we care about is not selling the  
20 product in France, what we care about is patient  
21 safety, so what we should do is send over a request to  
22 Dr. Barbolt and say, Dr. Barbolt, what does this mean  
23 clinically, at least preclinically in animals as it  
24 relates to safety?

25 MR. THOMAS: Object to the form of the



Confidential - Subject to Protective Order

Page 437

1 question.

2 BY MR. THORNBURGH:

3 Q. That discussion isn't in here, right?

4 A. That's correct.

5 Q. Kammerer is not saying let's look out for  
6 patient safety, let's do a preclinical study of  
7 particle loss in patients, let's get Dr. Barbolt  
8 involved and see what this means clinically or pre  
9 clinically to the safety of patients, right?

10 MR. THOMAS: Object to the form of the  
11 question.

12 THE WITNESS: Could we take those one at  
13 a time. It seems like there are three or four  
14 questions there.

15 BY MR. THORNBURGH:

16 Q. Well, Kammerer is not saying in this document,  
17 let's look out for patient safety, that was number one,  
18 he's not saying that, right?

19 A. Can I respond? He's not saying that either.

20 Q. Right. What he's saying is, and if you look  
21 with me at the last section we were at -- you have that  
22 document, 01219629. So if you can pull up the  
23 paragraph that says, Jackie, we need some  
24 clarification, what he's saying here is under the  
25 standards that are being set, because TVT still has

Confidential - Subject to Protective Order

Page 438

1 very high percentage of particle loss, TVT will fail  
2 under the test, and he goes on to say, as it stands, we  
3 will not be able to sell in France next year, right?

4 MR. THOMAS: Object to the form of the  
5 question.

6 THE WITNESS: That's what he says in  
7 this memo.

8 BY MR. THORNBURGH:

9 Q. Right. So he's concerned about whether or not  
10 TVT is going to be able to be sold in France because of  
11 the particle loss issue, right?

12 MR. THOMAS: Objection.

13 THE WITNESS: I think that's one of his  
14 concerns.

15 (Document marked for identification as  
16 Deposition Exhibit No. T-2125.)

17 BY MR. THORNBURGH:

18 Q. Hand you what's been premarked as Exhibit 2125.  
19 This is a series of e-mails, and if you turn with me to  
20 Bates number ending 4493, you see at the bottom Herve  
21 Fournier sends to Gene Kammerer and a number of other  
22 folks a English PDF that was -- it says, here is a  
23 French version from which the English PDF text sent  
24 yesterday by AFNOR.

25 You see that?

Confidential - Subject to Protective Order

Page 439

1 A. Yes.

2 Q. And then Herve Fournier says in the document,  
3 it is stated that one soft elongation of 0.01 kN, which  
4 equals ten Newtons.

5 You see that?

6 A. No.

7 Q. So on the same page, 4493.

8 A. Okay. Coming up, okay, I see it.

9 Q. It says, in the document, it is stated that a  
10 one soft elongation of 0.01 kN or which equals, I  
11 guess, 10 Newtons, right, is applied instead of 10  
12 elongation of 25 Newtons as proposed by CL Medical!  
13 Even in this case 8.5% loss of particles is noted for  
14 TVT, right?

15 You see that?

16 MR. THOMAS: Object to the form of the  
17 question.

18 BY MR. THORNBURGH:

19 Q. So even in the case of one soft elongation pull  
20 at 10 Newtons -- sorry -- one soft elongation is  
21 applied instead of 10 elongation of 25 Newtons as  
22 proposed -- I'm sorry.

23 Basically, what it's saying is the standards  
24 are being relaxed here based on the other documents we  
25 have looked at what they're proposing is a one soft

Confidential - Subject to Protective Order

Page 440

1 elongation of 10 Newton pull, right?

2 MR. THOMAS: Object to the form of the  
3 question.

4 THE WITNESS: I see that it's written  
5 here.

6 BY MR. THORNBURGH:

7 Q. Instead of what they were proposing before,  
8 which was 10 elongation of 25 Newtons, right?

9 A. So that was the draft, that version, I guess,  
10 this is the final.

11 Q. By then even in this case were 10 Newtons of  
12 pull, only one soft pull would apply, 8.5% of particle  
13 loss is still noted for TVT?

14 MR. THOMAS: Object to the form of the  
15 question.

16 THE WITNESS: That's what it says.

17 BY MR. THORNBURGH:

18 Q. So Gene Kammerer says, as you see above, this  
19 data at 10 Newton times one and 8.5% particle loss does  
20 not sound correct to me. Our testing has consistently  
21 shown about 1% loss of weight. As I mentioned  
22 previously we use different parameters to define the  
23 test. That is, we pull to a specific distance, rather  
24 than a force. But we also measure by loss of weight  
25 and only do one pull.

Confidential - Subject to Protective Order

Page 441

1           So he is still concerned saying, wait, this  
2 doesn't sound right to me, we still can't be seeing  
3 8.5% particle loss at one pull at 10 Newtons, right?

4           MR. THOMAS: Object to the form of the  
5 question.

6           THE WITNESS: He's saying that the  
7 procedure used in-house is a different one than what is  
8 recommended by the AFNOR guidance.

9 BY MR. THORNBURGH:

10 Q.       So if you go up to next Page 4492, see where it  
11 says concerning fraying?

12           You see where I'm at?

13 A.       Yes.

14 Q.       Concerning fraying (to be typed by AFNOR) the  
15 CL Medical/Pariente project is as follows, it have not  
16 been possible to have one Newton.

17           So what Gene Kammerer was saying, no, we'll  
18 just do one Newton because that's what that Lin article  
19 showed, so let's just do one Newton, and this person is  
20 writing to Gene and saying we can't do one Newton.  
21 It's not going to be allowed.

22           To have been unfortunately decided for the time  
23 being despite our efforts one elongation of 10 Newtons  
24 on the slings and no excluding limit of 5% weight loss.  
25 Is this fine with you?

Confidential - Subject to Protective Order

Page 442

1           And if you turn the page -- I read that  
2     correctly, right?

3                   MR. THOMAS: Object to the form of the  
4     question.

5     BY MR. THORNBURGH:

6     Q.           That's what that paragraph --

7     A.           You did read it correct. I'm stumbling on the  
8     no excluding limit of 5% weight loss. What does that  
9     mean? That it's not a hard requirement but --

10    Q.           Yeah, it looks like maybe all the industry  
11    pushed by Ethicon may have worked at AFNOR?

12                   MR. THOMAS: Object to the form of the  
13    question. Quit arguing and being disrespectful.

14                   MR. THORNBURGH: I'm not arguing or  
15    being disrespectful.

16                   MR. THOMAS: Sure you are.

17                   THE WITNESS: This is a cold document to  
18    me. I'm not part of this e-mail stream. This is an  
19    area outside of my area of expertise. Right now trying  
20    to read through it and understand and get into the  
21    context of this discussion, what happened, I'm really  
22    not that kind of person that you ought to be asking  
23    questions about this document about.

24    BY MR. THORNBURGH:

25    Q.           Right, but, I mean, my point is here is that,

Confidential - Subject to Protective Order

Page 443

1     you know, it's like there's 8.5% particle loss, and you  
2     were a person at preclinical who had a discussion and  
3     was involved about this particle loss issue, and  
4     instead of just accepting the fact that there's  
5     particle loss at 8.5% and having you work up a  
6     preclinical study on that issue, what we see here is  
7     excuses and objections about why we shouldn't follow  
8     the protocols that have been set forth. What we should  
9     do is we should try to reduce or get rid of the 5%  
10    standard at AFNOR, and we should say that the study  
11    that's being done isn't good. We should lower the  
12    number of pulls, and we should lower the Newtons of the  
13    pull, right?

14                   MR. THOMAS: Object to the form of the  
15    question or object to the closing argument.

16    BY MR. THORNBURGH:

17    Q.           That's what we see here, right? I mean, as  
18    you've seen from all these e-mails we looked at, there  
19    was a decision not to have you get involved in doing  
20    preclinical studies on particle loss, right?

21                   MR. THOMAS: Object to the form of the  
22    question.

23    BY MR. THORNBURGH:

24    Q.           We didn't see any of that discussion in the  
25    exhibits we looked at, right?

Confidential - Subject to Protective Order

Page 444

1 MR. THOMAS: Object to form of the  
2 question.

3 THE WITNESS: That's why I'm wondering  
4 why you're asking me all these questions about  
5 something that I was only peripherally involved with,  
6 maybe even just verbally and never in any kind of  
7 document where I would weigh in with my opinion.

8 BY MR. THORNBURGH:

9 Q. Right. Well, the point is, though, like you  
10 doing all the justification memos about why testing  
11 shouldn't be done and you testified earlier that you  
12 should look at the worst case scenario, instead of  
13 doing that, what we see is objections to standards that  
14 are being proposed by AFNOR, and instead of accepting  
15 the study protocol that had been done by Pariente and  
16 its findings, trying to come up with a way to show that  
17 there's less particle loss with the TVT slings, right?

18 MR. THOMAS: Object to form of the  
19 question.

20 BY MR. THORNBURGH:

21 Q. That's what we're seeing here, right?

22 MR. THOMAS: Object to the form of the  
23 question.

24 THE WITNESS: I don't see it that way.

25 BY MR. THORNBURGH:



Confidential - Subject to Protective Order

Page 445

1 Q. Okay, well, you did see instead of accepting  
2 the protocol -- the study protocol, Gene Kammerer tried  
3 to come up with a less rigid study, which would show  
4 less particle loss, right?

5 MR. THOMAS: Object to the form of the  
6 question.

7 THE WITNESS: I don't know the context.  
8 It sounds like he was providing input based on his own  
9 biomechanical engineering experience. I can only  
10 surmise.

11 BY MR. THORNBURGH:

12 Q. He proposed one pull instead of ten pulls,  
13 right?

14 MR. THOMAS: Object to form of the  
15 question.

16 THE WITNESS: I can only surmise that he  
17 thought that that was the relevant conditions for the  
18 test.

19 BY MR. THORNBURGH:

20 Q. And instead of 25 Newtons, he proposed one  
21 Newton, right?

22 MR. THOMAS: Object to the form of the  
23 question.

24 THE WITNESS: Same answer.

25 BY MR. THORNBURGH:

Confidential - Subject to Protective Order

Page 446

1 Q. That's what we've seen in these records, right?

2 MR. THOMAS: Object to the form of the  
3 question.

4 THE WITNESS: You can read in these  
5 e-mails.

6 (Document marked for identification as  
7 Deposition Exhibit No. T-2126.)

8 BY MR. THORNBURGH:

9 Q. Handing you what's been premarked as Exhibit  
10 2126. I'm going to turn your attention to the last  
11 page. It's Bates Number 00844331. It says it's from  
12 Yukie Yamano, who appears to be, as you can see,  
13 from -- well, as you'll see, it's an Ethicon employee  
14 from Japan. It says, Joe, do you have time to talk on  
15 this today? Any time in the afternoon is fine for me.  
16 This is a little complicated and urgent matter. One of  
17 our customers reported WHLW (government) as TVT  
18 complication after making a bladder calculus. Because  
19 the surgeon think end of strand of TVT is frayed, gets  
20 into the bladder and made bladder calculus.

21 You see that?

22 A. Yes.

23 Q. MHLW asked us if we received this kind of  
24 report or not worldwide basis. We would like to talk  
25 more to explain.

Confidential - Subject to Protective Order

Page 447

1           And then Joseph Megan responds, sends an e-mail  
2 to Dave Robinson, who's in clinical affairs, right?

3       A.       I think Dave was the medical affairs officer  
4 for Gynecare.

5       Q.       So he sends it to the medical affairs officer,  
6 a clinician, right?

7       A.       Yes.

8       Q.       And he says, hi Dave, quick question (I think)  
9 for Japan. A surgeon there has filed a complaint  
10 saying that the fraying of the TVT has caused a bladder  
11 calculus. (I'm not sure if the terminology is 100%  
12 right with translation.) Based on my discussion with  
13 Yamano-san, it seems that maybe there was a technique  
14 problem here or something, and maybe a bladder injury  
15 was not recognized right away. But we have to check  
16 out the fraying issue as the surgeon filed a complaint.

17           So we're gonna -- we think it's something else,  
18 but we got it -- now that a surgeon has filed a  
19 complaint, now we've got to check out this fraying  
20 issue, right?

21                   MR. THOMAS: Object to the form of the  
22 question.

23 BY MR. THORNBURGH:

24       Q.       That's what this appear to say?

25                   MR. THOMAS: Object to the form of the

Confidential - Subject to Protective Order

Page 448

1 question.

2 THE WITNESS: Well, so the question  
3 again?

4 BY MR. THORNBURGH:

5 Q. Yeah, well, the question here is, you know,  
6 what we see here is this Japanese employee of Ethicon  
7 is sending an e-mail saying there's a doctor that's  
8 complained that as a result of fraying of the mesh,  
9 there's been an injury, a bladder calculus to a  
10 patient, right?

11 A. It's a product complaint, yes, I see that.

12 Q. And we see Joseph Megan saying, oh, it's  
13 probably physician related, but now that the surgeon  
14 has filed a complaint, now we've got to check out the  
15 fraying issue, right?

16 MR. THOMAS: Object to the form of the  
17 question.

18 THE WITNESS: I see that.

19 BY MR. THORNBURGH:

20 Q. And it says has the fraying been linked to any  
21 complications? Bladder related? My understanding is  
22 no. Please let me know, and he gives his voice mail.

23 You see that?

24 A. Yes.

25 Q. If you go up, Dave Robinson says, the fraying

Confidential - Subject to Protective Order

Page 449

1 of the original tape has proven to be of no consequence  
2 and cannot cause a calculus unless the tape is in the  
3 bladder or urethra. Three scenarios often account for  
4 this finding. Tape truly in bladder at time of TVT but  
5 not recognized with cysto. Tape in a bladder wall and  
6 therefore difficult to recognize with cysto. The tape  
7 or at least the edge of the tape later erode into the  
8 bladder and a calculus forms. Tape is placed properly  
9 but later erodes into the bladder and a calculus forms.

10 You see that?

11 A. Yes, I see that.

12 Q. These scenarios can happen with tape from any  
13 manufacturer and none of them have anything to do with  
14 the fraying that occurs with our original tape, right?

15 You see that?

16 A. Yeah, I would agree with that, not as a  
17 clinician but this makes -- it's logical. It's a  
18 logical conclusion.

19 Q. Dear Dave, thank you very much for the answer  
20 to our question. I shared your comment with our  
21 colleagues and we have another question. According to  
22 your e-mail, the fraying of the original tape has  
23 proven to be of no consequence and cannot cause a  
24 calculus unless the tape is in the bladder or urethra.  
25 Does Gynecare have any clinical paper or data for this?

Confidential - Subject to Protective Order

Page 450

1 If yes, could you please provide it to us. Regards,  
2 Yukie.

3 You see that?

4 A. Yes.

5 Q. So then Dave Robinson responds, do you mean  
6 papers regarding no calculus formation without tape in  
7 the bladder (no papers to support) or that the fraying  
8 is of no consequence --

9 A. Hang on.

10 Q. Okay. See David Robinson's response to --

11 A. Okay. Which page?

12 Q. On 4332.

13 MR. THOMAS: When you read would you  
14 please read in a monotone, as opposed to giving  
15 intonations to the statement as if you're talking like  
16 the person is. That's the way all of your questions  
17 have been, and I think it's more appropriate to read  
18 cold monotone as opposed to any intonations.

19 BY MR. THORNBURGH:

20 Q. You see where I'm at, the e-mail from David  
21 Robinson on August 30th, 2007?

22 A. Yes.

23 Q. And it says, "do you mean papers regarding no  
24 calculus formation without tape in the bladder (no  
25 papers to support) or that the fraying is of no

Confidential - Subject to Protective Order

Page 451

1 consequence (there may be internal data on file but  
2 there will be no published information). The internal  
3 data will probably only support the fact that the  
4 frayed pieces remain biocompatible."

5 That's where you come in right?

6 MR. THOMAS: Object to the form of the  
7 question.

8 THE WITNESS: That's his clinical  
9 judgment. Yeah, okay.

10 BY MR. THORNBURGH:

11 Q. So Yukie Yamano writes back, Dear Dave, thank  
12 you very much for your response. I mean whether there  
13 is data which the frayed piece is not consequence and  
14 no possibility of causing of calculus formation. If  
15 the internal data may only support the fact that frayed  
16 pieces remain biocompatible, we may not get the answer  
17 we are looking for. Our QA, that's quality assurance,  
18 right? On the next page, our QA and safety department.  
19 You see where I'm at, on Bates Number 43332?

20 A. Okay.

21 Q. Our QA and safety department is asking the  
22 following questions also. We would appreciate if you  
23 provide comments from clinical standpoint. We are also  
24 trying to get the comments from several incontinence  
25 experts in Japan. Is there any possibility of frayed

Confidential - Subject to Protective Order

Page 452

1 pieces of TVT floats (moves) into the bladder without  
2 any bladder injury? If the above question is yes and  
3 the frayed pieces go into the bladder, is there any  
4 possibility the frayed piece can be the core (cause) of  
5 calculus formulation. We would highly appreciate and  
6 your help on this. Thank you and best regards Yukie,  
7 right?

8 So Yukie is asking too many questions. He's  
9 saying --

10 MR. THOMAS: Oh, please, Dan. Come on.  
11 Would you ask a straight question, please.

12 MR. THORNBURGH: I'm asking a straight  
13 question.

14 MR. THOMAS: No, you're not. You're  
15 laughing when you say it.

16 BY MR. THORNBURGH:

17 Q. Yukie has asked additional questions, hasn't  
18 he?

19 MR. THOMAS: Object to form of the  
20 question.

21 THE WITNESS: It looks like there's some  
22 follow-up questions.

23 BY MR. THORNBURGH:

24 Q. Okay. And so now he's trying to get more  
25 specific and trying to get additional explanation for



Confidential - Subject to Protective Order

Page 453

1 what the possible safety issues are to patients if the  
2 TVT frays float or migrate into the bladder, right?

3 A. Yes, that's his question.

4 Q. So you Dave writes, dear Yukie, the answer to  
5 your first question is no. I will forward your  
6 question to Tom Barbolt for further input.

7 You see that?

8 A. Yes.

9 Q. Do you remember this discussion?

10 A. No, I -- so what he's forwarding to me then is  
11 the question, if the phrase --

12 MR. THOMAS: He hasn't showed you  
13 anything yet that he forwarded to you.

14 BY MR. THORNBURGH:

15 Q. Yeah, my question to you is do you recall this  
16 discussion? I've got your responses.

17 A. I don't recall this specifically discussion,  
18 not even copied on the e-mail.

19 Q. Well, let's see if that ever happened.

20 A. Okay.

21 Q. So what I have done is I've marked 2127.

22 (Document marked for identification as  
23 Deposition Exhibit No. T-2127.)

24 BY MR. THORNBURGH:

25 Q. Which is a additional e-mail about this

Confidential - Subject to Protective Order

Page 454

1 discussion. Can you look at -- if you look through  
2 this document on page 4342, 4343 and 4344, you'll see  
3 that that's the string of e-mails that we just  
4 discussed which were questions and attempts at  
5 answering Yukie Yamano questions, right?

6 A. Yes.

7 Q. And then it looks like on 4342, it says, David  
8 Robinson is the person sending -- forwarding you the  
9 e-mail, e-mails that we've just discussed on Friday,  
10 August 31st, 2007 to you and to Yukie Yamano. "Asking  
11 TVT Complication? - Fraying" is the subject line,  
12 right?

13 Dear Tom, can you help with any info regarding  
14 the lack of impact regarding frayed edges. Thank you  
15 for your help.

16 And then you write on the next page, 4341, I  
17 think your three scenarios are correct, Dave. It is  
18 not biologic plausible -- sorry -- it is not  
19 biologically possible -- I think you meant not  
20 biologically possible, right?

21 MR. THOMAS: Object to the form of the  
22 question.

23 THE WITNESS: It is not biologically  
24 possible.

25 BY MR. THORNBURGH:

Confidential - Subject to Protective Order

Page 455

1 Q. Biologically possible for the filaments of the  
2 TVT tape to cause urinary calculi unless they are in  
3 contact with the urine in either the bladder or the  
4 urethra. I know of no preclinical (or clinical)  
5 studies examining the question as it is well accepted.

6 Number one, that doesn't completely answer  
7 Yukie's questions. One of his questions was if the  
8 frayed piece is loose can it migrate into the bladder  
9 causing a bladder calculi, right?

10 MR. THOMAS: Object to form of the  
11 question.

12 THE WITNESS: I don't see that in this  
13 e-mail string.

14 BY MR. THORNBURGH:

15 Q. Did David Robinson not forward to you the full  
16 question from Yukie?

17 A. I don't know. I don't recall that.

18 Q. So you never did a pre -- you never did a  
19 preclinical study that looked at the potentiation of a  
20 frayed, loose, migrating piece of the tape going into  
21 the bladder and causing a bladder calculi, correct?

22 A. Yeah, I know I'm not -- I know of no such  
23 preclinical study.

24 Q. I mean, it's possible if you've got these loose  
25 particles or loose, frayed pieces of the tape, it's

Confidential - Subject to Protective Order

Page 456

1 possible that the body will try to push that particle  
2 or that loose, frayed piece out of the body, and it  
3 could come into contact with the bladder causing a  
4 bladder calculi, right?

5 MR. THOMAS: Object to the form of the  
6 question.

7 THE WITNESS: I'm not a clinician;  
8 however, I do agree with the three scenarios that Dave  
9 had proposed. I think he was correct.

10 BY MR. THORNBURGH:

11 Q. I don't know that answered my question, sir.  
12 My question to you was you never studied whether or not  
13 it was possible for these loose particles or for loose,  
14 frayed pieces of the mesh to migrate into the bladder  
15 causing a bladder calculi, right?

16 MR. THOMAS: Object to the form of the  
17 question.

18 THE WITNESS: I think it's highly  
19 unlikely, given the thickness of the muscular wall of  
20 the bladder.

21 BY MR. THORNBURGH:

22 Q. That wasn't my question.

23 My question was you never studied that issue  
24 specifically?

25 A. That's correct.

Confidential - Subject to Protective Order

Page 457

1 Q. I mean, it's like if I get a splinter in my  
2 finger, and sometimes it can go down deep, my body  
3 usually either tries to gobble it up and sometimes it  
4 just disappears. Oftentimes, though, it gets pushed,  
5 it gets migrated out of my finger, out of my body as  
6 part of the inflammatory foreign body response, right?

7 MR. THOMAS: Object to the form of the  
8 question.

9 THE WITNESS: Well, a foreign body in  
10 the vicinity of the surface of the skin and a foreign  
11 body embedded in the pelvic fascia is really a  
12 different location.

13 BY MR. THORNBURGH:

14 Q. Right. But my question is in that example that  
15 I gave you about the splinter, the body can move it,  
16 can migrate that splinter outside of my body, right?

17 A. What the body does is create an inflammatory  
18 reaction to the splinter, it heals underneath the  
19 splinter, and then the splinter comes to the surface as  
20 the skin exfoliates it.

21 MR. THORNBURGH: We've got to go off the  
22 record.

23 THE VIDEOGRAPHER: We're going off the  
24 record. The time is 11:50 a.m.

25 (Brief recess.)